

JAN 13 2006

K053460

## 510(k) SUMMARY

### Device Name

<i>Classification Name:</i>	Catheter, Peripheral, Atherectomy 21 CFR §870.4875, Class II
<i>Common and Usual Name:</i>	Catheter, Peripheral, Atherectomy
<i>Proprietary Name:</i>	SilverHawk Peripheral Plaque Excision System

### Predicate Device

The SilverHawk Peripheral Plaque Excision System (K043553), currently marketed by FoxHollow Technologies, Inc. (Redwood City, CA).

### Summary

This summary of Special 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The SilverHawk Peripheral Plaque Excision System is intended for atherectomy of the peripheral vasculature and is not intended for use in the coronary or carotid vasculature. The SilverHawk Peripheral Plaque Excision System consists of two major components which are packaged separately, but used together during atherectomy procedures. The two components are the SilverHawk Peripheral Catheter and SilverHawk Cutter Driver.

The SilverHawk Peripheral Plaque Excision System will be provided sterile for single-use. The catheter will be sterilized by Ethylene Oxide (ANSI/AAMI/ISO 11135), including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of  $10^{-6}$ . The cutter driver is sterilized by Gamma Sterilization Cycle (ANSI/AAMI/ISO 11137), providing a minimum SAL of  $10^{-6}$ , with a minimum dose of 25kGy, using the VDmax method. The device is biocompatible per ISO-10993-1.

The SilverHawk Peripheral Plaque Excision System is substantially equivalent in material of construction, overall design, intended use, and safety and efficacy to the predicate device. The subject device was shown to have substantially equivalent performance when compared to the predicate device.

The SilverHawk Peripheral Plaque Excision System with labeling modifications is considered substantially equivalent to the SilverHawk Peripheral Plaque Excision System (K043553).

Contact:

Date: January 5, 2006

Melissa Murphy  
Regulatory Specialist  
FoxHollow Technologies, Inc.  
740 Bay Road  
Redwood City, CA 94063  
(650) 421-8579



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 13 2006

FoxHollow Technologies, Inc.  
c/o Ms. Melissa Murphy  
Regulatory Specialist  
740 Bay Road  
Redwood City, CA 94063

Re: K053460  
SilverHawk Peripheral Plaque Excision System  
Regulation Number: 21 CFR 870.4875  
Regulation Name: Peripheral Atherectomy Catheter  
Regulatory Class: Class II (two)  
Product Code: MCW  
Dated: December 9, 2005  
Received: December 13, 2005

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

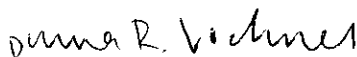
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-\_\_\_. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K053460

Device Name: SilverHawk Peripheral Plaque Excision System

Indications For Use:

The SilverHawk Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The catheter is not intended for use in the coronary or carotid vasculature.

Prescription Use   X  

AND/OR

Over-The-Counter Use

                      
(Part 21 CFR 801 Subpart D)

                      
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Vachon  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K053460